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December 13, 1999

FDA
Document Branch (H.F.A.-305)
New Line Food & Drug Administration
5630 Fisher Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 97-M-484S

To Whom It May Concern:

It has come to my attention that the FDA is considering instituting regulatory measures that would allow for the treatment of allograft as medical devices. The safety of bone allograft is borne out over a long and extensive history of their use. It seems to me that increasing the bureaucracy around this issue of surgery would not result in increased safety at all, and in fact, would only increase the cost substantially. The government, insurance companies, and our medical societies have pushed the cost factor of medicine to the forefront of our consciousness over the years. I would urge the FDA to do its part in holding down costs by limiting unnecessary bureaucratic regulations.

Respectfully submitted, .

Anthony A. Salerni, M.D.

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